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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,160	10/30/2003	De Chao Yu	CELL-023	9850

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EXAMINER	
GUZO, DAVID	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/698,160	YU ET AL.	
	Examiner	Art Unit	
	David Guzo	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/17/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Specifically, a sequence appears on page 6 of the specification which is not identified by SEQ ID NO or portion of a SEQ ID NO. If the sequence is a portion of a SEQ ID NO in the current Sequence Listing, the sequence must be identified by reciting for example, "nucleotides ---- to ---- of SEQ ID NO:----". Any response to this Office Action which does not include complete compliance with the Sequence Rules will be considered non-responsive.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 18 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed host cell as defined by the specification (see for example page 19) includes human cells which contain the claimed adenovirus vector wherein the cells can be *in vivo*. The claimed cell is present or intended to be present in a human being, said cell becoming integrated into the human being and therefore being an inseparable part of the human itself. The scope of the claim, therefore, encompasses a human being, which is non-statutory subject matter.

As such, the recitation of the limitation "non-human" or "host cell *in vitro*" or "an isolated host cell" would be remedial. See 1077 O.G. 24, April 21, 1987.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 10, 14, 15 and 17-18 are rejected under 35 U.S.C. 102(a) as being anticipated by Chia et al.

Both applicants and Chia et al. (cited by applicants, Proc. Amer. Assoc. For Cancer Res., Vol. 43, March 2002, see entire abstract) both recite a replication-competent (conditionally replication competent) adenovirus vector comprising a Epstein Barr virus (EBV) specific TRE (ori-FP) comprising FR enhancer sequences and a CMV minimal promoter operably linked to a adenoviral coding region (minus it's endogenous promoter) essential for replication (E1a) as well as host cells containing said vector. Chia et al. indicates that the vector is being used in *in vivo* studies and hence must be in a pharmaceutically acceptable excipient. Chia et al. therefore teaches the claimed invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 8-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants claim a replication competent adenoviral vector comprising a gene essential for adenovirus replication under transcriptional control of a EBV specific transcriptional regulatory element (TRE). Applicants define a "EBV specific transcriptional response element" as an element that "preferentially directs gene expression in EBV-associated cancer cells". The term is construed to read on any transcriptional response element (i.e. an EBV element or a cellular TRE or another viral element, etc.) that is preferentially active in EBV associated cancer cells. The claims therefore read on a genus of EBV specific transcriptional response elements in the adenoviral vectors. Applicants provide a written description for EBV TREs which are EBV specific transcriptional response elements.

The written description requirement for a genus may be satisfied by sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that applicant was in possession of the claimed invention. In the instant case applicants only disclose EBV TREs which preferentially

direct gene expression in EBV-associated cancer cells. Applicants disclose no non-EBV TREs which preferentially direct gene expression in EBV-associated cancer cells. Applicants present no disclosure of the relevant identifying characteristics of non-EBV TREs, i.e. applicants do not disclose how the sequences in the EBV TREs relate to non-EBV sequences (no structure-function analysis is presented) which would have the same properties of preferentially directing gene expression in EBV-associated cancers. Given applicants disclosure, the skilled artisan would be unable to envision the non-EBV members of the claimed genus and said artisan would conclude that applicants were not in possession of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 and 6 are vague in the recitation of the phrase "sequence derived from". The metes and bounds of the claimed subject matter are unclear because it is unclear how closely related to the starting sequence the sequences "derived from" said starting sequence are. Applicants do not recite the methodologies by which the sequences were derived and hence the metes and bounds of the sequences are unclear.

Claims 12-13 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 12-13 depend directly or indirectly from claim 1. Claim 1 recites an adenoviral vector comprising an adenoviral gene essential for replication of the adenovirus under control of the EBV TRE. Claims 12-13 do not further limit the subject matter of claim 1 because said claims recite that the adenoviral genes under control of the EBV TRE can be any (essential or non-essential) adenoviral genes.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo
June 19, 2006

DAVID GUZO
PRIMARY EXAMINER